



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Bulk Manufacturer of Controlled Substances Application: Janssen Pharmaceutical, Inc.

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration in accordance with 21 CFR 1301.33(a) on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION:

The Attorney General has delegated her authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Deputy Assistant Administrator of the DEA Office of Diversion Control (“Deputy Assistant Administrator”) pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on November 12, 2015, Janssen Pharmaceutical, Inc., 1440 Olympic Drive, Athens, Georgia 30601 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

| <u>Controlled Substance</u> | <u>Schedule</u> |
|------------------------------------|------------------------|
| Methylphenidate (1724) | II |
| Oxycodone (9143) | II |
| Hydromorphone (9150) | II |
| Hydrocodone (9193) | II |
| Oripavine (9330) | II |
| Thebaine (9333) | II |
| Oxymorphone (9652) | II |
| Tapentadol (9780) | II |
| Fentanyl (9801) | II |

The company plans to manufacture the above-listed controlled substances in bulk for distribution to its customers.

Dated: February 16, 2016.

Louis J. Milione,
Deputy Assistant Administrator.